such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: April 18, 1952. A plea of guilty having been entered, the court imposed a fine of $500 and a sentence of one year in prison. The prison sentence was suspended, and the defendant was placed on probation for 2 years.

3767. Misbranding of Alberty products. U. S. v. Various Quantities * * *. Answer filed by claimant; Government's motion to strike certain portions of claimant's answer granted in part. Judgment for Government. Decree of condemnation. (F. D. C. No. 24186. Sample Nos. 6221-K to 6249-K, incl.)

LIBEL FILED: December 22, 1947, Western District of Pennsylvania.

ALLEGED SHIPMENT: Between the approximate dates of March 26 and November 10, 1947, by Alberty Food Products, from Hollywood, Calif.

PRODUCT: 44 cans of *Instant Alberty Food*, 46 cartons of *Alberty's Food Regular*, 17 bottles of *Alberty's vitamin B complex tablets*, 38 bottles of *Alberty's Vio-Min vitamin-mineral tablets*, 18 bottles of *Alberty Garlic and Vegetable Oil perles*, 36 bottles of *Alberty's Lebara pellets, Homeopathic*, 66 bottles of *Alberty's Lebara No. 2 pellets*, 12 bottles of *Alberty's Oxorin tablets*, 72 cartons of *Pandora tablets*, 72 bottles of *Alberty's Phosphate pellets*, 228 bottles of *Alberty Phloxo B tablets*, 36 bottles of *Recal tablets*, 36 bottles of *Alberty's Riol tablets*, 36 bottles of *Alberty's Sabinol pellets*, 6 cartons of *Alberty's Special Formula tablets*, 24 cartons of *Alberty's Vegetable Compound capsules*, 192 cartons of *Alberty's vitamin A (high potency) shark liver oil*, 60 bottles of *Alberty's vitamin B_1 with other B complex factors*, and 54 cartons of *wheat germ oil perles* at Pittsburgh, Pa.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in a large number of diseases, symptoms, and conditions for which the articles were prescribed, recommended, and suggested in booklets entitled "Dynamic Digests" and "Health Mysteries," which were disseminated and sponsored by and on behalf of the manufacturer, packer, and distributor of the articles.

Further misbranding (*Alberty's Lebara pellets, Homeopathic, Alberty's Lebara No. 2 pellets, Alberty's Phosphate pellets*, and *Alberty's Sabinol pellets*), Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use since the directions for use in the labeling failed to state the diseases, symptoms, or conditions for which the articles were directed to be taken.

DISPOSITION: Upon agreement by the parties, an order was entered on November 4, 1948, directing the removal of the case to the District of Columbia. Thereafter, the Alberty Food Products, claimant, filed an answer denying that the products under seizure were misbranded, and alleging certain defenses as described in the opinion set forth below. A motion to strike such defenses from the answer was filed by the Government, and on March 25, 1949, after consideration of the briefs and arguments of counsel, the court handed down the following opinion:

MOORE, *District Judge:* "On October 19, 1948, the government filed a libel against various quantities of articles alleged to be articles of drug and to have been shipped in interstate commerce by Alberty Food Products, a co-partnership. Various dates of shipment are alleged, beginning March 26, 1947, and ending November 10, 1947. The libel charges misbranding, within the meaning of Section 352 (f) (1) of the Federal Food, Drug and Cosmetic Act. (21 U. S. C. A. 301 et seq.) Different bases for the allegations of misbranding are alleged with reference to different shipments. They fall into three groups. As to one group of shipments, it is alleged that they were misbranded because they did not contain in the labeling a statement listing various diseases and ailments of the human body as to which they were claimed to possess therapeutic value, in two booklets disseminated by the manufacturer, packer and distributor, denominated respectively 'Health Mysteries' and 'Dynamic Digest.' Another group is alleged to be misbranded for lack of the same information in the labeling, but with reference to 'Dynamic Digest' alone. The third group is alleged to be misbranded, not only because its labeling contains no reference to the diseases for which claims are made in 'Health Mysteries' and 'Dynamic Digest,' but also because the labeling contains no directions for use other than a designated quantity and frequency of dosage.

"Alberty Food Products on December 2, 1948, filed its answer to the libel, setting up, among other defenses, (A) that Section 352 (f) (1) of the Act does not sustain the allegations of the libel for the reason, as claimant avers, that the provision that the labeling contain 'adequate directions for use' does not require that the labeling of a drug state the diseases or conditions of the body for which the drug when used as directed will be effective, nor does it require that the labeling of a drug state each of the diseases and conditions of the body for which the drug is advertised as a therapeutic treatment; (B) that the dissemination of the booklets 'Health Mysteries' and 'Dynamic Digest' has been abandoned by the claimant following cease and desist orders of the Federal Trade Commission heretofore issued against the claimant on the ground that the booklets contain false advertising; (C) that the labeling upon each of the articles prescribes maximum quantity and dosage, and therefore satisfies the requirements of Section 352 (f) (1) of the Act, and (D) that the booklet entitled 'Dynamic Digest' was not disseminated prior to August 15, 1947, whereas some of the articles alleged to be misbranded for lack of information in the labeling about diseases and ailments concerning which claims are made in 'Dynamic Digest' were alleged to have been shipped in interstate commerce prior to that date.

"The government has moved to strike the above defenses from the answer on the ground that they are insufficient in law, and on the further ground as to some of them that they are immaterial.

"The relevant portions of the Act, together with the interpretive regulation with reference thereto issued by the Commissioner of Food and Drugs on December 22, 1939, as amended April 10, 1941, are as follows:

> Section 352: "A drug or device shall be deemed to be misbranded * * * (f) Unless its labeling bears (1) adequate directions for use; * * *"
>
> Section 334: "(a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *"
>
> 21 C. F. R. Cum. Supp. Section 2.106: "(a) Directions for use may be inadequate by reason (among other reasons) of omission, in whole or in part, or incorrect specification of:
>
> > (1) Directions for use in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or in such other conditions, if any there be,

for which such drug or device is commonly and effectively used; * * *"

"It is clear from the terms of the Food, Drug and Cosmetic Act, as well as from its legislative history, that Congress intended, insofar as the Act relates to drugs, to provide effective safeguards for the public in their use of such articles, by requiring that all drugs shipped in interstate commerce be labeled in such fashion that the consumer thereof shall be given all information reasonably necessary for the intelligent use of the drug in self-medication. H. R. 2139, 75th Cong., 3 Sess. p. 8.

"It is obvious that in the use of drugs for self-medication the health of the consumer may be endangered in any of three ways: First, if the drug is misbranded either by omission from the labeling of a statement of its ingredients, or by false statements in the labeling with reference to the contents of the package, or with reference to the efficacy of the drug in the treatment of certain diseases; secondly, if the drug is placed on the market with no mention in the labeling of any disease or ailment for which the manufacturer intends it to be used as a cure or palliative, while at the same time the manufacturer falsely advertises it to the public through other means as having therapeutic value in certain diseases; and, thirdly, if the labeling mentions some diseases or ailments for which the drug is claimed to be a remedy, while the manufacturer falsely advertises to the public by other means that it is a remedy for other and different diseases and ailments. The peril to public health from the first of these means is apparent from its mere statement, and Congress has provided protection against the danger in Section 352 (a) of the Act. It is perhaps not so clearly apparent from the other two means. Nevertheless the danger therein is real and substantial. Where no diseases or ailments whatever are mentioned in the label, if the consumer who purchases the product is one who is not aware of the advertised claims he is left to speculate without guide as to the diseases or conditions for which it is intended to be used, and therefore may use it for some condition in which it is neither effective nor intended to be so, but may be harmful. If the consumer is aware of the advertising, he is led to purchase the drug for self-medication in some disease or condition for which it is not effective, and may be hurtful. In the third situation, a consumer who has knowledge of the advertiser's claims may purchase the drug for use, not for an ailment specified in the labeling, but in some disease or condition for which the advertiser falsely claims it is efficacious, though not mentioned in the labeling; and in such case, if the advertiser's advice be followed, the result is the same as in the second situation. A purchaser is led into a form of self-medication which is of no benefit to him, which may be directly harmful, and which is further deleterious to his health because of the fact that it deters or prevents him from seeking other means of relief.

"The section of the statute under consideration must be construed in the light of the underlying Congressional purpose, and so as to give effect to the Act as a whole, if a reasonable construction can be arrived at which may accomplish that end.

"The words, 'adequate directions for use,' necessarily relate to some purpose which is to be served by the use, and that purpose must be consistent with the intent of the Act as a whole to protect the public health. For what purpose are drugs used? Obviously, as a remedy for some ailment of the body. It seems equally obvious that no drug can be said to contain in its labeling adequate directions for its use, unless every ailment of the body for which it is, through any means, held out to the public as an efficacious remedy be listed in the labeling, together with instructions to the user concerning the quantity and frequency of dosage recommended for each particular ailment. See the following unreported cases, cited in the government's brief: *United States* v. *150 pkgs.* * * * *Bush Mulso Tablets*, (E. D. Mo.) No. 4415, C. C. H. Food and Cosmetic Law Reports, § 7059; *United States* v. *516 cases* * * * *Nue-Ovo*, (S. D. Col.) No. 7418, C. C. H. Food, Drug and Cosmetic Law Reports, § 7091.

"It may be that compliance with this requirement, thus freeing the shipper from any liability under Section 352 (f) (1), would result in the drug being misbranded under Section 352 (a) of the Act; and doubtless this is the precise result which was intended in those cases where false and misleading advertising claims are made which are omitted from the labeling.

"Any other construction of Section 352 (f) (1) would provide the manufacturer and shipper with a convenient loophole through which he could evade the Act with resulting danger to public health. He need only include in the labeling either dosage directions alone, or with the addition of one or more bodily diseases or ailments for which he claims the drug is efficacious, and by a contemporaneous advertising campaign lead the public to believe that the drug is a remedy for a multitude of ailments. In such cases, if claimant's first and third defenses be good, there is no section of the Act which protects the public against the resulting harm.

"I am not impressed by the argument of counsel for claimant that the administrative interpretation hereinbefore set out sustains his construction of Section 352 (f) (1). Keeping in mind the Congressional intent, I am of opinion that the clear meaning of the Administrator in this interpretive regulation is that not only the dosage, but the disease or diseases for which such dosage is recommended or advertised, must appear in the labeling if the labeling is to be held to bear adequate directions for use. This conclusion finds support in the unreported case of *United States* v. *Colgrove*, (S. D. Cal.) cited in the government's brief as No. 5992, C. C. H. Food, Drug and Cosmetic Law Reports, § 7046, in which case the District Court granted an injunction restraining defendants from introducing into interstate commerce any product without a label bearing adequate directions for use of such product in the treatment of all ills for which it was advertised, which directions were to include the dosage to be taken in each of such conditions.

"Paragraphs (A) and (B) of claimant's first defense in the answer to the libel, and the third defense therein, will therefore be stricken as insufficient defenses.

"It will next be considered whether the alleged fact that the booklet, 'Dynamic Digest,' was not disseminated prior to August 15, 1947, if true, is a defense to the allegation that certain articles of drug which were shipped prior to that date were misbranded for lack of inclusion in the labeling of the names of the diseases and ailments for which they were recommended for use in 'Dynamic Digest,' together with directions for their use in such ailments. All but five of the articles of drug mentioned in the libel were advertised in both 'Health Mysteries' and 'Dynamic Digest,' with substantially the same recommendations and representations with respect to their remedial and curative qualities. One of the five shipments as to which the allegations are based solely on claims made in 'Dynamic Digest' was made after August 15, 1947. As to another of the five, the allegation of misbranding is based not only on claims made in 'Dynamic Digest,' but also on omission from the labeling of any directions for use other than mere prescription of the quantity and frequency of dosage. Therefore, the words 'but avers that "Dynamic Digest" was not disseminated by it prior to August 15, 1947,' appearing in Paragraphs 21, 22, 23, 27, 29, 33, 34, 35, 36, 38, 39, 41 and 42 of the fourth defense will be stricken as immaterial.

"This leaves for consideration three articles of drug advertised only in 'Dynamic Digest,' of which some shipments were made prior to August 15, 1947, with respect to which the sole basis of the libel is that claims of therapeutic qualities as to certain diseases were made in 'Dynamic Digest.'

"It is my opinion that the drugs in these particular shipments could not be said to be misbranded under the terms of Section 352 (f) (1) by reason of omission from the labeling of those diseases and ailments for which the drugs had not been held out in any way to the public as cures or palliatives prior to the respective dates of shipment. Therefore, I will overrule the motion to strike the words 'but avers that "Dynamic Digest" was not disseminated by it prior to August 15, 1947,' appearing in Paragraphs 25, 31, and 43, of the fourth defense, insofar as they relate to those shipments of the three articles of drug last referred to made prior to August 15, 1947. Of course, the government may still prevail in its charge that these drugs were misbranded, if it can prove that it was the intention of the shipper at the time of shipment to make the claims for them which were afterwards made in 'Dynamic Digest'; but this proof cannot rest alone on the fact that 'Dynamic Digest' was subsequently disseminated.

"Finally, with reference to the second defense, namely, that dissemination of the booklets 'Health Mysteries' and 'Dynamic Digest' has been abandoned by the claimant, it does not appear from any of the pleadings that the booklets are

alleged to have been abandoned prior to the shipping date of any of the shipments which were seized. Their abandonment after shipments were made could constitute no defense to the allegation of misbranding, since under the Act misbranded drugs may be seized at any time after they are shipped in interstate commerce. 21 U. S. C. A. 334. Therefore, the motion to strike the second defense will be sustained as the pleadings now stand. However, I believe that if the answer were amended to show that the abandonment of dissemination of the booklets took place before the date of some or all the shipments, this would be a good defense, at least conditionally, as to those shipments which were subsequent to the abandonment. I say conditionally, because it is only to the extent that the abandonment of such dissemination creates an inference that the shipper did not intend, when it shipped the drugs in interstate commerce, that they be used for the treatment of the diseases named in the booklets, that the abandonment can be said to be effective as a defense. The government might introduce evidence to show that, notwithstanding such abandonment, it was still the intention of the shipper that the drugs be used for the treatment of the diseases mentioned in the booklets; but in the absence of such proof, it is my opinion that the abandonment would warrant the inference that there was no intent to misbrand as to drugs shipped thereafter.

"One of the arguments advanced by claimant is that since the Federal Trade Commission has been given authority by Congress to prevent false advertising, whereas such authority has been denied to the Food and Drug Administration, it should be held that the Federal Trade Commission is the only agency of government which can operate in this field. But it is well settled that the action of either of these agencies—that of the Food and Drug Administration relative to misbranding, and that of the Federal Trade Commission relative to false advertising—is not the exclusive remedy afforded to the government in a case where both misbranding and false advertising are present. In other words, the fact that the government may seize an article because it is misbranded does not prevent the Federal Trade Commission from issuing a cease and desist order with reference to false advertising concerning that article; and conversely, the issuance of a cease and desist order does not prevent the government from proceeding against the article because of the misbranding. *United States* v. *5 Cases of Capon Springs Water*, (C. C. A. 2, 1946) 156 F. (2d) 493; *United States* v. *Research Laboratories*, (C. C. A. 10, 1942) 126 F. (2d) 42, Cert. denied 317 U. S. 656.

"An order may be entered in accordance with this opinion."

On April 14, 1949, pursuant to the above opinion, an order was entered granting in part and denying in part the Government's motion to strike. On January 9, 1950, a request for admissions of certain facts was served by the Government upon the claimant, pursuant to Rule 36 of the Rules of Civil Procedure; and on March 20, 1950, an answer to the request was submitted. Thereafter, motions for summary judgment were filed on behalf of the Government and the claimant. On February 5, 1951, it appearing to the court that there existed no genuine issue as to any material fact, an order was entered denying the claimant's motion and granting the Government's motion for summary judgment, and ordering that the products be condemned and destroyed.

An appeal taken to the United States Court of Appeals for the District of Columbia was dismissed on or about June 18, 1952. On July 1, 1952, the products were destroyed.

3768. Misbranding of Vigorettes. U. S. v. 169 Dozen Bottles, etc. (F. D. C. No. 33251. Sample Nos. 8418-L, 8419-L.)

LIBEL FILED: May 15, 1952, Western District of New York.

ALLEGED SHIPMENT: Between the approximate dates of March 24 and May 1, 1952, from Cleveland, Ohio.